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Section 5: 510(k) Summary

Submitted by:	The Procter & Gamble Company 6110 Center Hill Avenue Cincinnati, OH 45224
Contact Person:	Mark M. Anderson, Ph.D. Regulatory Affairs Manager (513) 634-5196 (voice) (513) 634-7364 (FAX)
Date Summary Prepared:	September 1, 2006
Trade Name:	TAMPAX® Compak Pearl Plastic Applicator Scented Tampons and TAMPAX® Compak Pearl Plastic Applicator Unscented Tampons
Common Name:	Scented Menstrual Tampon Unscented Menstrual Tampon
Classification Name:	Scented or Scented Deodorized Menstrual Tampon (21 CFR 884.5460) Unscented Menstrual Tampon (21 CFR 884.5470)
Predicate Devices:	TAMPAX® Compak Compact Plastic Applicator Tampons - Scented and Unscented Tambrands, Inc., K880023 (Regular Absorbency); K880022 (Super Absorbency)

NOV 22 2006

Device Description: The device is a conventional menstrual tampon consisting of an absorbent pledget, a withdrawal cord, and an applicator. It is available in both scented and unscented versions.

- The absorbent pledget consists of a scented or unscented pad of rayon fibers overwrapped with a non-woven fabric. A cotton withdrawal cord is sewn to the pad, and the pad is compressed into a traditional bullet-shaped pledget.
- The formed pledget is inserted into a plastic applicator consisting of an inner pusher tube and an outer insertion tube with a closed, rounded tip.
- Each tampon is wrapped in an individual plastic film wrapper and packaged in sealed multi-unit containers for retail sale.

Intended Uses: These devices are intended to be inserted into the vagina to absorb menstrual fluid.

Technological Characteristics: These devices are similar to the predicate devices in terms of component materials, overall design and labeling. These devices incorporate a change in the fragrance (scented version), changes in the colorants used in the plastic applicators, changes in the dimensions of the pad of absorbent fibers, and a change in the pledget overwrap configuration.

Safety Assessment: A battery of safety tests was conducted, including *in vitro* microbiological testing, biocompatibility testing and extraction testing, to evaluate the safety profile of the 510(k) devices. The results of these safety tests support the conclusion that these 510(k) devices are equally as safe as the predicate devices.

Effectiveness: TAMPAX® Compak Pearl Plastic Applicator Scented Tampons and TAMPAX® Compak Pearl Plastic Applicator Unscented Tampons comply with the syngyna absorbency requirements of 21 CFR 801.430. Therefore, additional testing of these tampons is not necessary to establish their equivalence to the predicate tampons in terms of effectiveness.

Conclusions: The results of evaluations of these devices support the conclusions that they are safe for their intended use and that they are substantially equivalent to the cited predicate devices with regard to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

NOV 2 2 2006

Mark M. Anderson, Ph.D.
Regulatory Affairs Manager
The Procter & Gamble Company, The Winton Hill Business Center
Product Safety & Regulatory Affairs
6110 Center Hill Avenue
CINCINNATI OH 45224

Re: K062638
Trade/Device Name: TAMPAX® Compak Pearl Plastic Applicator Scented/Unscented Tampons
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampons
Regulatory Class: II
Product Code: HIL and HEB
Dated: November 6, 2006
Received: November 7, 2006

Dear Dr. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known): K062638

Device Name: TAMPAX® Compak Pearl Plastic Applicator Scented Tampons and TAMPAX® Compak Pearl Plastic Applicator Unscented Tampons

Indications for Use:

TAMPAX® Compak Pearl Plastic Applicator Scented Tampons and TAMPAX® Compak Pearl Plastic Applicator Unscented Tampons are menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Sayerman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062638